Oncotype DX Prostate
Order Form and Statement of Medical Necessity

Tel. 866.ONCOTYPE | oncotypeDX.com

Genomic Health® | oncotypeDX® Genomic Prostate Score

Complete and Fax to 650.362.6487

ONCOTYPE DX PROSTATE CANCER ASSAY

The clinical information provided below will be utilized to calculate the patient's risk group as defined in NCCN® guidelines (2016 v.3). The resulting NCCN risk group will appear on the test report.

STUDY INFORMATION /CODE

PATIENT INFORMATION

Patient Name (Last, First, MI)

❑ Male ❑ Female

DOB (mm/dd/yyyy)

Medical Record / Patient # (If applicable)

Address

City State Zip Country

Primary Phone Alternative Phone (Optional)

CLINICAL INFORMATION (complete all)

Pre-Biopsy PSA ng/mL

Prostate Volume

Stage
❑ T1c ❑ T2a ❑ T2b ❑ T2c

Gleason Score (Primary + Secondary)
❑ 3+3 ❑ 3+4 ❑ 4+3*

Prostate Biopsy Cores

a) # of Cores Collected

b) # of Positive Cores

c) Max % tumor involvement in any core
❑ ≤ 50% ❑ > 50%

d) * # of 4+3 Positive Cores

Pre-Oncotype DX GPS management recommendation?
❑ Radical Prostatectomy
❑ External Beam Radiation
❑ Brachytherapy
❑ Active Surveillance
❑ Other

ORDERING INFORMATION

Practice Account Name

Ordering Physician Name Fax Email

Contact Name Contact Phone Contact Email

Additional Physician / Recipient Name

Email

Phone Fax

BILLING INFORMATION

Submitting Diagnosis ❑ Prostate Cancer ❑ Other _____ **Select ICD-10 Code** ❑ C61 ❑ Other _____

Select Billing Type ❑ Medicare ❑ Private Insurance ❑ Medicaid ❑ Patient ❑ Pathology Account (Restricted to contracted accounts)

Facility where procedure was performed (Medicare only) ❑ In-Office ❑ Hospital Outpatient ❑ Hospital Inpatient - Discharge Date _____

Primary Insurance Company Name Member ID# Prior Authorization#

Secondary Insurance Company Name (If applicable) Member ID# Prior Authorization#

Include a copy of the front and back of the patient's insurance card(s).

PATIENT CONTACT

Genomic Health will serve as an advocate to patients during the billing process which may require us to contact the patient directly.

❑ Check the box if the patient IS AWARE OF A DIAGNOSIS OF PROSTATE CANCER and Genomic Health is authorized to contact the patient.

SPECIMEN RETRIEVAL

Genomic Health will obtain the specimen on your behalf. Check box if location is listed on attached pathology report, or indicate location of specimen in the fields provided below.

❑ Reference attached pathology report.

Location of Specimen Phone Fax Contact Name

PHYSICIAN SIGNATURE & ATTESTATION

Your signature constitutes a Statement of Medical Necessity (SOMN) and your attestation of the following: 1) accurate clinical information has been entered above, as this information will be used by GHI to automatically calculate the patient's risk group (as indicated in NCCN 2016 v.3) and inaccurate information could impact the test results; 2) if the diagnosis or exception criteria sections of the form do not indicate otherwise, the patient meets the assay criteria (see reverse); 3) the test is medically necessary and test results will be used with other clinical data to help determine the appropriate treatment plan for the patient; and 4) the patient has consented for this test to be performed, and for Genomic Health Inc. to release test information when necessary to obtain reimbursement.

For Medicare Beneficiaries: You further certify that you have completed requisite training and have enrolled in the Genomic Health CTR Program and that the patient meets the Medicare patient eligibility criteria provided on the reverse side of this form.

Ordering Physician Signature Print Physician Name Date (mm/dd/yyyy)

Exception Criteria/Comments

PATHOLOGY INFORMATION | PATHOLOGY TO COMPLETE

Pathology Account

Submitting Pathologist Name

Phone Fax

SUBMIT SPECIMEN WITHIN 24 HOURS

Specimen ID

Date of Collection (mm/dd/yyyy)

Date Block Pulled From Archive (Medicare only)

Specimen Barcode
Affix Specimen barcode here

GHI007, Rev #25

Pathology Comments:

No substitutions for this assay

Include a pathology report with specimen submission

REQUISITION FORM INSTRUCTIONS

Online ordering is available at online.genomichealth.com. For assistance in setting up a Portal Account for online ordering, please contact Customer Service. Assay results will be delivered to the Ordering Physician and additional recipients via the secure online portal and/or by fax based on the physicians' report delivery preferences on file at Genomic Health, Inc. (GHI). To establish or change report delivery preferences, please contact Customer Service at 866.662.6897.

The result report is based upon GHI's analysis of the submitted specimen and information provided on the Requisition Form. Additional materials or information that may have been submitted with the specimen are not considered in analyzing the specimen or preparing the report.

CLINICAL INFORMATION

Enter the clinical information for your patient. This information will be utilized to calculate the patient's risk group as defined in NCCN guidelines (2016 v.3). The resulting NCCN risk group will appear on the test report.

ORDERING INFORMATION

Additional physician/recipient information is optional. If another physician is responsible for the care of this patient and has requested a copy of the result, enter the applicable information in the spaces provided under this section.

BILLING INFORMATION

A. Indicate the party responsible for payment.

B. Billing Type:
   - » All Medicare patients will have an eligibility check and may be contacted during the process. If Patient is selected, a representative will contact the ordering physician's office to collect payment information.
   - » If the patient's insurance is Medicare, select the location where the procedure was performed. If Inpatient, enter the date of discharge from the hospital.
   - » Before selecting Bill Pathology Account, verify with GHI that you have a contracted account on file.

C. Complete the Primary and Secondary Insurance Information fields.

D. Include a copy of the front and back of both the primary and secondary insurance cards.

CLINICAL CRITERIA

A. All

The results of the Onco*type* DX Prostate Cancer Assay are applicable to newly diagnosed and biopsied prostate cancer patients in one of the following three risk groups:

NCCN Very Low Risk (must meet ALL of the following criteria):

- Gleason Score ≤ 6 (Grade Group 1)
- PSA < 10 ng/mL
- Clinical stage T1c
- Fewer than 3 positive biopsy cores, ≤ 50% tumor involvement in any core
- PSA density < 0.15 ng/mL/g

NCCN Low Risk (must meet ALL of the following criteria):

- Gleason Score ≤ 6 (Grade Group 1)
- PSA < 10 ng/mL
- Clinical stage T1c-T2a

NCCN Intermediate Risk (must meet ONE of the following):

- Gleason Score ≤ 6 (Grade Group 1), AND
  - » Clinical stage T2b-T2c, AND/OR
  - » PSA 10-20 ng/mL
- Gleason Score 3+4 (Grade Group 2), AND all of the following:
  - » Clinical stage T1c-T2c
  - » PSA ≤ 20 ng/mL
- Gleason Score 4+3 (Grade Group 3), AND all of the following:
  - » Clinical stage T1c-T2c
  - » PSA ≤ 20 ng/mL
  - » Only 1 positive core of 4+3 disease

B. Medicare

The Onco*type* DX Prostate Cancer Assay is covered only when all of the following clinical conditions are met:

- Needle biopsy with localized adenocarcinoma of the prostate (no clinical evidence of metastasis or lymph node involvement)
- Biopsy consistent with the NCCN Prostate Cancer Early Detection guidelines (2016 v.3)
- Patient risk group is defined as:
  - » Very Low Risk Disease OR Low Risk Disease (see definitions above); OR
  - » Favorable Intermediate Risk Disease (must meet one of the following):
    - ▪ Gleason Score ≤ 6 (Grade Group 1), AND
      - ◆ Clinical stage T1c – T2a, AND
      - ◆ PSA < 20 ng/mL
    - ▪ Gleason Score ≤ 6 (Grade Group 1), AND
      - ◆ Clinical stage T2b – T2c, AND
      - ◆ PSA < 10 ng/mL
    - ▪ Gleason Score 3+4 (Grade Group 2), AND
      - ◆ Clinical stage T1c – T2a, AND
      - ◆ PSA < 10 ng/mL
- Patient's life expectancy is > 10 years based on the Social Security Actuarial tables
- Patient is a candidate for, and is considering conservative management and would be eligible for definitive treatment (radical prostatectomy, radiation therapy or brachytherapy)
- Patient has not received pelvic radiation or androgen deprivation therapy prior to the biopsy
- Patient is monitored for disease progression according to active surveillance guidelines as recorded in NCCN guidelines
- Physician must report the development of metastasis or prostate specific cancer mortality in patients who were deemed Very-Low, Low, or Favorable Intermediate Risk Disease by the assay and pursued active surveillance.

C. In some cases, additional assessment methods may be used to verify that the specimen meets the criteria for the assay.

PATIENT CONTACT

A. Select the box if the patient is aware of his prostate cancer diagnosis and the Ordering Physician is authorizing Genomic Health to contact the patient directly regarding his financial responsibility.

NOTE: Third-party reimbursement is affected by many factors. Genomic Health Inc. makes no representation or guarantee that full or partial insurance reimbursement or any other payment will be available. While Genomic Health tries to provide correct information, we make no representations or warranties, expressed or implied, as to the accuracy of the information. These support services have no independent value to providers and are included within the cost of the Onco*type* DX® testing services.

SPECIMEN RETRIEVAL

If indicated, GHI will request the retrieval of the appropriate specimen for the ordered assay on your behalf.

NOTE: If the specimen retrieval section is not completed and the specimen is not submitted with the Order Form and Statement of Medical Necessity, GHI assumes you will initiate the retrieval of the specimen.

PHYSICIAN SIGNATURE & ATTESTATION

Sign and date the Order Form and Statement of Medical Necessity and print your name. The signature must be of an Ordering Physician (treating physician or pathologist) or his/her representative. If this order form is completed by the Physician's representative, the patient's medical record must contain the signed order from the Ordering Physician.

PATHOLOGY INFORMATION

A. Enter the identification number for the most representative specimen (i.e. the longest linear length of the highest grade tumor) on the appropriate line.

B. While the GHI laboratory can accept tumor blocks and unstained slides, blocks are preferred.

C. Include a copy of the pathology report with the Specimen Kit submission box. The pathology report may be used for reimbursement and/or administrative purposes.

SUBMIT REQUISITION FORM TO GENOMIC HEALTH

A. Fax the completed, signed Requisition Form to the fax number indicated on the reverse side.

B. If submitting a specimen, include the Requisition Form with the specimen collection kit. See specimen preparation and shipment instructions.

SPECIMEN INSTRUCTIONS

Specimen Preparation Instructions

A. For specimen criteria and specimen preparation instructions, visit onco*type*DX.com.

B. Please send either:
   - » One fixed paraffin embedded tumor block.
   - » Eight 5 µm serial unstained slides.

IMPORTANT: Hand number the serially sectioned slides to indicate the order in which they were cut. Unnumbered slides will be returned.

C. Formalin is the preferred fixative. Tissues processed in other fixatives should not be submitted.

D. Label all specimens with barcode labels from the Specimen Collection and Transportation Kit. Affix a coinciding barcode in the designated area on the Order Form. (Discard any remaining barcodes; do not use for future submissions.).

E. Label the specimens with an additional patient-specific identifier (e.g. patient name, date of birth, hospital number, order number, accession number). All specimens require two patient-specific identifiers for processing.

F. If you have any questions, please contact customer service at the phone number listed on the front side of this form.

DOMESTIC SHIPPING INSTRUCTIONS

A. Before shipping, make a copy of the Order Form and Statement of Medical Necessity and retain it for your records.

B. Place the Onco*type* DX Specimen Kit into the FedEx® Clinical Pak.

C. Complete the FedEx® US Airbill. The airbill is pre-printed with Genomic Health shipping information.

D. Seal the Clinical Pak by removing the plastic adhesive protector from the white strip and secure.

E. Place the package in the designated FedEx® pickup location at your site.

F. If your site does not have standard FedEx® pickup, call 800-GO FEDEX (800-463-3339) to arrange for pick up.

NOTE: To order additional kits, email Customer Service at customerservice@genomichealth.com.